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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,353	05/01/2001	Steven L. Stice	P 0280612	2602

909 7590 05/28/2002
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EXAMINER

CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,353

Applicant(s)

STICE ET AL.

Examiner

Deborah Crouch

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-35 and 47-77, drawn to a method of cloning a mammal; a fetus; a transgenic fetus; a chimeric fetus; offspring of the fetus, the transgenic fetus and the chimeric fetus; progeny of the fetus, the transgenic fetus and the chimeric fetus; a method of producing a CICM cell line; a CICM cell line; differentiated cell lines and organs, classified in class 435, subclasses 172.3 and 325, and class 800, subclass 2.
- II. Claims 36-45, drawn to a method of treating Parkinson's Disease comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- III. Claims 36-45, drawn to a method of treating Huntington's Disease comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- IV. Claims 36-45, drawn to a method of treating Alzheimer's Disease comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- V. Claims 36-45, drawn to a method of treating ALS comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- VI. Claims 36-45, drawn to a method of treating spinal cord defects or injury comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- VII. Claims 36-45, drawn to a method of epilepsy comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- VIII. Claims 36-45, drawn to a method of treating multiple sclerosis comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- IX. Claims 36-45, drawn to a method of treating muscular dystrophy comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- X. Claims 36-45, drawn to a method of treating cystic fibrosis comprising administering a xenogenic cell, classified in class 424, subclass 93.2.

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- XI. Claims 36-45, drawn to a method of treating liver disease comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- XII. Claims 36-45, drawn to a method of treating diabetes comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- XIII. Claims 36-45, drawn to a method of treating heart disease comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- XIV. Claims 36-45, drawn to a method of treating cartilage disease or defect comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- XV. Claims 36-45, drawn to a method of treating burns comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- XVI. Claims 36-45, drawn to a method of treating foot ulcers comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- XVII. Claims 36-45, drawn to a method of treating vascular disease comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- XVIII. Claims 36-45, drawn to a method of treating urinary tract diseases comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- XIX. Claims 36-45, drawn to a method of treating AIDS comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- XX. Claims 36-45, drawn to a method of treating cancer comprising administering a xenogenic cell, classified in class 424, subclass 93.2.
- XXI. Claims 46 and 78, drawn to a method of producing a pharmaceutically active protein, classified in class 800, subclass 4.

The inventions are distinct, each from the other because:

Inventions I and any one of II-XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

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product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pigs of invention I can be used to produce organs for transplantation.

Inventions I and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pigs of invention I can be used to produce organs for transplantation.

Inventions II-XIX are mutually exclusive methods of treating various diseases. Each of the claimed diseases comprises separate and materially different symptoms, and would require materially different and separate protocols for treatment. Further, the treatment of any one of these diseases is not needed for the implementation of the treatment for any other of the diseases.

Inventions II-XIX and XX are to mutually exclusive and independent methods. None of inventions II-XIX are required for the implementation of invention XX, and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of Claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126. The examiner's SPE is Deborah Reynolds, whose telephone number is (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Art Unit Patent Analyst, Ms. Pauline Farrier, whose telephone number is (703) 305-3550.

The fax number is (703) 308-4242.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800 / 1632

Dr. D. Crouch
May 22, 2002